SLOVENSKI STANDARD
SIST EN ISO 7886-1:2000

01-januar-2000

Sterilne podkožne injekcijske brizge za enkratno uporabo - 1. del: Injekcijske brizge za ročno injiciranje (ISO 7886-1:1993, vključno s tehničnim popravkom 1:1995)

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:1993, including Technical Corrigendum 1:1995)

Sterile Einmalspritzen für medizinische Zwecke - Teil 1: Spritzen zum manuellen Gebrauch (ISO 7886-1:1993, einschließlich Technische Korrektur 1:1995)

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Seringues hypodermiques stériles, non réutilisables - Partie 1: Seringues pour utilisation manuelle (ISO 7886-1:1993, Rectificatif Technique 1:1995 inclus)

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Ta slovenski standard je istoveten z: **EN ISO 7886-1:1997**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 7886-1:2000 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7886-1

May 1997

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Descriptors: see ISO document

English version

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:1993, including Technical Corrigendum 1:1995)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Foreword

The text of the International Standard from ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 205 'Non-active medical devices', the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1997, and conflicting national standards shall be withdrawn at the latest by November 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice

The text of the International Standard ISO 7886-1 : 1993 including Technical Corrigendum 1:1995, has been approved by CEN as a European Standard without any modification.

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NOTE : Normative references to international publications are listed in annex ZA (normative).

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Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1 : General requirements	EN 20594-1	1993
ISO 3696	1987	Water for analytical use - Specification and test methods	EN ISO 3696	1995
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times	EN 28601	1992

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INTERNATIONAL STANDARD

ISO 7886-1

First edition
1993-10-01

Sterile hypodermic syringes for single use —

Part 1: Syringes for manual use

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Seringues hypodermiques stériles, non réutilisables —
Partie 1: Seringues pour utilisation manuelle

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Reference number
ISO 7886-1:1993(E)

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Annexes

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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International Standard ISO 7886-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

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This first edition of ISO 7886-1 cancels and replaces ISO 7886:1984. It was decided to divide the Standard into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 (in course of preparation) being applicable to sterile, single-use syringes for use with power-driven syringe pumps. The major differences between this part of ISO 7886 and ISO 7886:1984 are as follows.

a) In order to reflect the demand for syringes of sizes other than those listed in ISO 7886:1984, this part of ISO 7886 does not specify a range of syringe sizes and allows the syringes to be marked with graduations at greater than the nominal capacity.

b) An informative annex on forces required to operate the syringe plunger has been introduced.

c) The tests for toxicity given in ISO 7886:1984 have been replaced by an informative cross-reference to ISO 10993-1.

d) The informative annex on test methods for compatibility between syringes and injection fluids has been revised.

e) This part of ISO 7886 permits the use on package labelling of the ISO symbol for "do not re-use", but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

— *Part 1: Syringes for manual use*

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— *Part 2: Syringes for use with syringe pumps*

Annexes A, B, C and D form an integral part of this part of ISO 7886. Annexes E, F, G, H and J are for information only.

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Introduction

This part of ISO 7886 does not give requirements or test methods for freedom from biological hazard. Guidance on biological tests relevant to hypodermic syringes is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the syringes are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Materials to be used for the construction of syringes are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. Guidance on some aspects of the selection of materials is given in annex E.

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The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling the primary container. It is not practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in annex F. These test methods can be regarded only as a means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

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Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. The types of material that have received wide acceptance are included in annex E. If an incompatibility exists, the injection should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers.

Hypodermic syringes specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

This part of ISO 7886 does not cover syringes for the injection of insulin (see ISO 8537).

In some countries, national pharmacopoeia or government regulations are legally binding and their requirements may take precedence over this part of ISO 7886.